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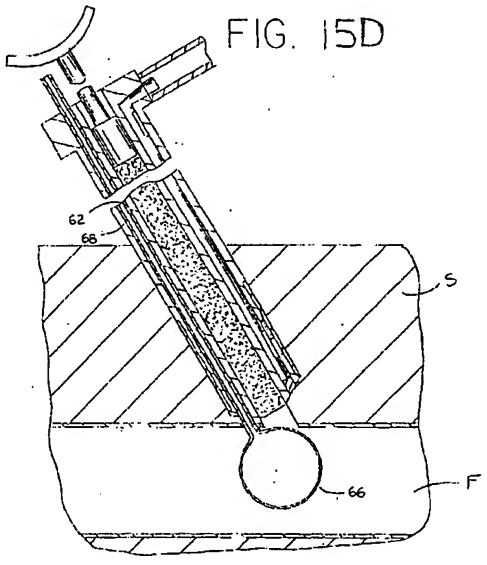
(54) Wound treating device

(57) The present invention relates to a wound treating device having a tubular portion (28) with proximal and distal ends (30 and 32) and at least one lumen (34) extending therebetween. An inflatable means is located at the distal end (32) of the tubular portion (28), and is made up of a flexible membrane (36). The inflatable means is positionable within the distal end (32) of the tubular portion (28) and is movable between a retracted position within the tubular portion and an inflated position to form a balloon-like projection which may be placed adjacent an aperture in a blood vessel to aid in slowing or stopping blood flow from the aperture.

In another embodiment of this invention, the elongated tube (28 or 72) of the wound treating device has proximal and distal end portions (30 or 76 and 32 or 74) and at least two lumens extending between the proximal and distal ends. The first lumen (68) is adapted to receive a flow control device (60) so that the flow control device (60) may be partially positioned within the blood vessel for providing local flow control at the aperture in the blood vessel. The flow control device (60) has a tubular portion (62) with an inflatable membrane (66) attached at its distal end which defines a balloon-like portion when inflated. The balloon-like portion is adapted to control the flow of fluid through the aperture. An inflatable means is attached to the second lumen of the wound treating device's tubular portion. The inflatable means has a flexible membrane (36 or 84) carried generally adjacent its distal end portion (32 or 74) and is movable between a retracted position and an inflated position to form a balloon-like projection at the distal end of the wound treating device.

FIG. 15D



EP 1 159 982 A1

Description

Background

[0001] The present invention relates, in general, to devices for reducing and/or preventing an undesirable flow of fluid between two contiguous tissue areas, such as bleeding from a blood vessel after removal of a medical device, catheter system, or the like. More particularly, the present invention concerns a novel wound treating device which includes means for depositing a treating agent at a wound or aperture between two contiguous tissue areas, such as depositing a clotting or hemostatic agent at the opening in a blood vessel or the like following removal of a medical device or instrument therefrom.

[0002] Many medical procedures, including both therapeutic and diagnostic procedures, often require access between two contiguous tissue areas, such as through the skin and into the vascular system of the patient. As an example, although various means may be used to obtain access into a vein or artery, typically access is obtained by inserting a cannula or catheter (called an introducer catheter or sheath) through the skin and into the selected blood vessel. A medical or diagnostic instrument, such as a guide wire, guiding catheter, balloon angioplasty device, atherectomy device, or the like is then inserted into the vascular system through the introducer sheath.

[0003] Depending on the procedure, to permit the insertion of the diagnostic or therapeutic device therethrough, the introducer sheath must be of relatively large diameter. This, of course, results in a relatively large hole or aperture in the vessel wall. After the medical procedure is completed, however, this opening must be closed, and bleeding from the blood vessel stopped.

[0004] A common technique to stop such bleeding, as in cardiac balloon angioplasty procedures, is for a nurse or technician to manually apply direct and continuous pressure on the opening in the blood vessel until the blood clots. This may require an hour or more of medical personnel time. Unfortunately, when this procedure is utilized, there is also a significant chance that movement by the patient will reopen the opening and that it will begin bleeding again, resulting in a hematoma or other complications. Because of the risk of bleeding, patients are usually required to remain overnight in the hospital for rest and observation, thus greatly increasing the cost of the overall procedure.

[0005] One prior device for stopping bleeding from an aperture in a blood vessel is a type of expandable plug. The plug is pushed through the opening into the blood vessel and into the blood stream. Once in the blood stream, it expands. The expanded plug is then pulled back against the aperture where, because of its expanded size, it plugs the opening. Such a device may work satisfactorily, but requires inserting and leaving a foreign object in the vessel. It is usually medically preferable to avoid inserting and leaving objects in a vessel.

[0006] The wound treating device disclosed in U.S. Patent 5,129,882, overcomes many of the shortcomings of prior methods and devices used in wound closure. This device uses an exteriorly mounted, distally located inflatable membrane on a catheter, and is adapted to deliver a wound treating agent to the aperture site. Although this device is believed to be an advance over prior methods and apparatus, efforts continue to provide new and further improved apparatus and methods to address the problems described above.

[0007] Accordingly, it is a general object of the present invention to provide a novel wound treating device which is particularly useful in treating and assisting in treating wounds such as vascular wounds that result from insertion of a medical device, such as a catheter, and which does not suffer from the drawbacks described above.

Summary Of The Invention

[0008] In one embodiment of the present invention, the wound treating device comprises generally a tubular portion having a proximal end, a distal end and a lumen extending therebetween. An inflatable means in the form of a flexible inflatable membrane is positioned within the distal end of the tube and is movable between a retracted position within the distal end and an inflated position to form a balloon-like projection at the distal end of the tube. The proximal end of the tubular portion is adapted to receive means, such as, but not limited to, a syringe, for moving the inflatable means between the retracted position and the inflated position.

[0009] Inflation of the membrane may serve not only to retain the device at the desired location adjacent the wound site, but may also serve to apply a treating agent to the wound. The treating agent may, for example, be contained in a pocket formed by the membrane when it is located in the distal end of the tube, or it may be coated on the surface of the membrane. In either situation, the membrane preferably has any suitable release agent known in the art on the surface to permit ready release of the membrane after treatment.

[0010] In an alternative embodiment of the present invention, the wound treating device is adapted to be positioned adjacent to an aperture or other wound in a blood vessel for the purpose of treating and, in particular, promoting clotting and healing of the aperture or other wound. The wound treating device comprises an elongated tube having a proximal end portion, a distal end portion, and preferably at least two lumens extending therebetween. One of the lumens is adapted to receive a flow control device which may be partially positioned within a blood vessel for assisting in positioning the distal end of the wound treating device adjacent to the aperture and/or for providing local control of the flow of blood from the vessel aperture. An inflatable means, in the form of a flexible inflatable membrane located generally adjacent to the distal end portion, is coopera-

tively associated with the other lumen and is movable between a retracted position and an inflated position to form a balloon-like projection generally adjacent to the distal end.

[0011] To enhance clotting or healing of the vessel aperture, various other aspects of the present invention may be employed. For example, the membrane of the wound treating device may have a clot inducing surface, may have a treating material on its surface, or may actually expel a treating material from the lumen of the tube as it is inflated. Alternatively, a third lumen may be provided in the elongated tube from which or through which a treating material is discharged.

[0012] The flow control device of the present invention, referred to above, preferably has a tubular portion including proximal and distal end portions and a membrane attached to the distal end portion. The membrane is inflatable to form a balloon-like projection, which is to be located within the vessel and upon retraction against the aperture may help control the flow of blood from the vessel aperture and to enhance clotting as described more fully below.

[0013] These and additional features and advantages of the present invention will become more apparent from the following detailed description of the invention, as exemplified in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014]

Figure 1 is a fragmentary diagrammatic view of a sheath introducer extending through the skin into a femoral artery of a patient.

Figure 2 is an enlarged cross-sectional view of the proximal and distal end portions of a wound treating device, having an expandable retention and dispensing means in the form of a balloon membrane at the distal end.

Figure 3 is an enlarged cross-sectional view showing the wound treating device of Figure 2 in an advanced stage of dispensing a treating agent.

Figure 4 is an enlarged cross-sectional view showing the embodiment of Figure 2 after all the treating agent has been dispensed and the membrane inflated.

Figure 4A is an enlarged cross-sectional view of a one-way valve that may be used to maintain inflation of the membrane.

Figure 5 is a cross-sectional view of the distal end of the treating device in Figure 2 inserted into the skin, approaching a blood vessel.

Figure 6 is a cross-sectional view of the treating device of Figure 2 showing clotting agent being dispensed at the aperture of a blood vessel.

Figure 7 is a cross-sectional view of the treating device of Figure 2 showing the membrane fully inflated after the clotting agent has been dispensed, and being held against the wound.

Figure 8 is a cross-sectional view of the wound clotting device of Figure 2 showing the wound clotting device being removed from the aperture after deflation of the membrane.

Figure 9 is a cross-sectional view of the wound clotting device of Figure 2 used in conjunction with a sheath introducer.

Figures 10A-C show steps in applying a release agent and a treating agent to the surface of the membrane.

Figure 11 is a cross-sectional view showing the inflated membrane in a balloon-like shape having a release agent and a treating agent applied.

Figure 12 is a cross-sectional view of the membrane, the release agent and the treating agent positioned within the distal end of the tube.

Figure 13A is a cross-sectional view of the flow control device, with the membrane in a deflated and retracted position, that forms a part of the present invention.

Figure 13B is a cross-sectional view of the flow control device, with the membrane in an inflated position, that forms a part of the present invention.

Figure 14A is a cross-sectional view showing the proximal and distal ends of an alternate wound treating device of the present invention.

Figure 14B is a cross-sectional vew of the wound treating device of Figure 14A with the inflatable means being inflated and a treating agent being dispensed.

Figures 15A-F show, in sequential operative positions, the alternate embodiment of the wound treating device depicted in Figure 14A-B with the flow control device depicted in Figures 13A-B.

Figures 16A-C show an enlarged cross-sectional view, in sequential operative positions, of a further alternative wound treating device for use with the flow control device of Figure 13.

Figures 17A-D show, in sequential operative positions, the alternate embodiment of the wound treating device of Figure 16.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Figure 1 is a partial diagrammatic representation of a sheath introducer 20 which has been advanced through the skin surface S into a femoral artery F of a living patient. The sheath introducer 20 is shown in the femoral artery F for purposes of illustration only and not for purposes of limitation. It is understood that a sheath introducer can also be used in accessing other arteries, veins, or blood vessels, or in communicating between other contiguous tissue areas of a patient's body.

[0016] As shown in the exemplary procedure of Figure 1, the sheath introducer 20 is initially advanced through a patient's skin and into the artery F. The sheath introducer 20 has a resealable valve 22 located at its

proximal end 26, as is well known in the medical field. In the typical procedure, some type of medical device, for example, a guiding catheter, an angioplasty device, or the like, is inserted into the sheath introducer through the valve and advanced into the artery and then to the location of the procedure. After the medical device has been used, it is withdrawn from the artery and the sheath introducer. The sheath introducer 20 must then be removed from the artery F. This, of course, leaves an aperture or opening in the artery F. To assist in stopping bleeding from the opening in the artery, the wound treating device of the present invention may be utilized.

[0017] Figures 2-9 show one embodiment of the wound treating device of the present invention in an enlarged view. The device of Figure 2 includes an elongated tube 28, which extends between a proximal end portion 30 and a distal end portion 32. The tube also includes a hollow bore or lumen 34, which extends fully between the proximal and distal end portions.

[0018] The tube may be formed by extrusion from a suitable plastic such as nylon, polyproylene, or the like, although the present invention is not limited by the method of manufacture or the type of material, and injection molding or other materials could be used where feasible. The plastic material utilized in the manufacture of the tube should in any event, be sufficiently stiff so as to be capable of being advanced through an introducer cannula or sheath introducer, but not so stiff that it will cause damage to the tissue.

[0019] For dispensing a treating agent at the site of a wound and for retaining the device in the vicinity of the wound, a flexible membrane 36 is attached at the distal end 32 of the tube 28. The membrane preferably has the shape of a short balloon, open at one end for attachment to the tube and closed at the other end. Other shapes, however, may also be used without departing from the present invention.

[0020] The membrane is preferably made of a flexible plastic material of the type which is compatible with medical applications, such as silicone, polyethylene, polypropylene, polyurethane, latex or the like. Prior to use, the balloon is located in an inverted or invaginated position within the distal end of lumen 34. When in this position, the membrane forms a pocket, into which treating agent 38 may be placed. The treating agent 38 may be of any desired material, such as an antibiotic, thrombin or clotting agent, in powder, gel or other suitable form. The treating agent may be pre-inserted into the tube during the manufacturing process or may be added to the tube at the time of use. If pre-inserted during manufacture, a removable hermetic seal 40 may be provided by adhesive bond or other suitable attachment over the distal end of the tube to preserve the treating agent against degradation during storage. The seal may be removed prior to use, or may be made of a material which dissolves upon contact with liquid such as bodily fluids or blood encountered when inserting the device into position adjacent the wound site.

[0021] To dispense the treating agent, as shown in Figures 3 and 4, the lumen 34 is pressurized by liquid or gas to push or inflate the membrane, causing it to expel the treating agent from the distal end of the lumen. Preferably a syringe of typical construction having a barrel 42, plunger or piston 46 and male luer fitting 48, is used to pressurize the lumen. To accommodate such a syringe, a female luer connector fitting 50 is provided at the proximal end of the tube 28. The fitting 50 includes a through passageway 52 which directly communicates at one end with the lumen and communicates at the other end with a standard tapered female luer connector. Although a luer-slip or luer-lock connection may be used, the illustrated fitting 50 has external threads for threaded engagement with the syringe (to provide a luer-lock arrangement) which prevents inadvertent separation of the syringe and tube.

[0022] Figures 5-9 illustrate how the alternative device shown in Figures 2-4 may be used in treating a wound and, in particular, in assisting clotting of an opening in a blood vessel F. As shown in Figures 5-8, the device may be used with or without an introducer sheath, although the introducer sheath, shown in Figure 1, is normally preferred. The distal end of the tube is inserted through the skin S to the site of the opening or aperture A in the blood vessel F. As noted above, the tube 28 may be inserted through an introducer or it may be introduced through an opening in the skin provided by another instrument. The tube is inserted until the distal end is generally adjacent to the wound.

[0023] The lumen of the tube is then pressurized by high pressure liquid or air, preferably liquid, which is injected into the lumen from a syringe. The pressure forces the membrane outward, expelling the treating agent at the site of the wound, as shown in Figure 6. Continued application of pressure causes the membrane to expand to completely expel the treating agent 38 and form a balloon-like projection, as shown in Figure 7, which has several advantages. First, when fully inflated, the balloon-like projection serves to retain the tube in the desired position relative to the site of the wound. When used to assist clotting in blood vessels, the balloon-like projection further helps block blood flow from the vessel and applies pressure against the vessel opening. The pressure applied by the balloon may also be supplemented manually by user force exerted on the proximal end of tube 28.

[0024] To avoid the need to maintain pressure on the syringe, the wound clotting device may include a releasable one-way inflation valve positioned, for example, in the inflation lumen which would allow syringe to be removed and the balloon to remain inflated in a position against the hole in the artery to block blood flow without a medical attendant being present. Such a valve could be of any suitable known type, such as a flexible duckbill or diaphragm valve 56 located in the passageway 52 of luer fitting 50 as is illustrated, for example, in Figure 4A -- depicted in the closed position in solid lines and in the

open position in dashed lines.

[0025] After the treatment is completed, the balloon is deflated and the tube 28 withdrawn, as shown in Figure 8. To allow release of the membrane from the wound, the membrane is preferably coated with a non-stick release agent which will be described in more detail in reference to Figures 10-12.

[0026] Figure 9 depicts use of the alternate device in combination with a sheath introducer 20. When used with a sheath introducer, the tube 28 should be of sufficient length to extend beyond the distal end of the sheath to permit ejection of the treating agent at the wound site and to permit inflation of the membrane to form the balloon-like projection. Otherwise, the construction and operation of the alternate device with an introducer sheath is essentially as described above. Of course, when used with an introducer sheath which extends into the wound itself, e.g., into an access opening in a blood vessel, the sheath is normally withdrawn from the wound before the tube 28 is moved through the distal end of the sheath to dispense the treating agent.

[0027] Figures 10A-10C depict the application of the desired release agent and treating agent to the surface of the membrane 36. First, the membrane 36 is expanded to a balloon-like shape. The membrane is then dipped or inserted into a container containing a release agent 54, for example, a moisture activated release agent, such as a starch. The thickness of the release layer depends on the material chosen and the viscosity of the material at the time of application. The thickness is also dependent on the speed of hydration, which is a function of the mass of the release agent and the exposed surface area. It is presently believed that the preferred thickness of the release agent for a vascular wound, such as the incision in a blood vessel made for angiographic procedures, is approximately 10-50 mils.

[0028] The portion of the expanded membrane covered by the release agent is then placed in contact with a treating agent 38. A non-stick surface 44 such as Teflon material is preferably used to support the treating agent, and the inflated balloon is brought into contact with the treating agent so as to allow the agent to adhere to the surface, over the release agent. After the material on the membrane is dry as shown in enlarged dimension, for example, in Figure 11, the membrane is drawn, as by suction, into an invaginated position within the tube as shown in Figure 12.

[0029] Alternatively, the membrane 36 may itself be made of a material which has thrombogenic qualities, eliminating the need for a separate clotting agent. Specifically, the membrane could be made of a material having a specific activity which promotes clotting. It is understood that latex and some commercial grades of silicon rubber are naturally thrombogenic and promote clotting. Alternatively, other balloon materials, such as polyamide or PET, may be subjected to radiation or chemical treatment to increase surface activity to enhance clotting.

[0030] A further embodiment of the present invention comprises a wound treating device which further contains an additional lumen for receiving a flow control device that is partially positioned within the blood vessel for controlling flow through the aperture. As described in more detail below, the flow control device, in its illustrated embodiment, comprises a hollow tubular portion adapted to be received within the additional lumen, and a membrane attached to one end of the tubular portion to define a balloon-like portion within the vessel when inflated.

[0031] Further embodiments of the present invention are shown in Figure 13 in conjunction with either of the devices depicted and described in Figures 14 - 15 and Figures 16-17. The illustrated embodiment shown in Figure 13A comprises a flow control device 60 including a tubular member 62 of suitable plastic material or the like having a coextensive interior passageway 64. Elastic membrane 66, in the shape of a pouch and capable of repeated inflation and deflation without appreciable effect on the integrity of the walls of the membrane, is sealably attached at the distal end of the tubular member 62 to form a balloon which is inflatable by the introduction of pressurized fluid through the passageway 64. Figure 13B shows the membrane 66 in an inflated mode. Prior to inflation, the membrane is preferably disposed within the distal end of the interior passageway 64 for ease of insertion into the vessel, as described more fully below.

[0032] Figure 14A shows a first alternative embodiment of the wound treating or clotting device of the present invention equipped for use with the flow control device of Figures 13A and 13B. With reference to these figures, the wound treating device 70 comprises a tube, generally at 72, with a distal end portion generally at 74 and a proximal end portion generally at 76. A relatively large second lumen 82, a smaller inflation lumen 78 and a third lumen 68 extend between the proximal end 76 to the distal end 74 of the tube 72. The second and third lumens, 82 and 68, are open at the distal end, and the distal end of the inflation lumen is sealed closed.

[0033] The tube, as like the tube previously described in relation to Figures 2-9 above, may be formed by extrusion from a suitable plastic such as nylon, polypropylene, or the like. The plastic material utilized in the manufacture of the tube should in any event, be sufficiently stiff so as to be capable of being advanced through an introducer cannula or sheath introducer, but not so stiff that it will cause damage to tissue.

[0034] The inflation lumen 78 extends fully between the proximal end and distal ends of the tube 72. As noted above, the inflation lumen is sealed at the distal end and may carry a valve (not shown) at the other end, through which an inflation fluid, such as sterile water, may be injected. Such a valve is well known in medical product design and thus it will not be described in detail here. The diameter of the inflation lumen may vary, depending on the particular application. Typically, however, the di-

ameter should be sufficiently large to permit ready inflation of the inflatable means.

[0035] In the embodiment of the wound treating device shown in Figures 14A and 14B, an inflatable means 84 is located on the distal end 74 of the tube 72 for retention of the tube at the desired location and/or for applying a wound treating agent, although other types or forms of retention means may also be used for retaining the distal end of the clotting device at a selected position. In one form, the inflatable means 84 comprises a flexible sleeve located within a recessed area 96 at the distal end 74 of the tube 72. Each end of the sleeve is adhered or bonded to the surface of the tube, within the recessed area, to define an inflatable balloon portion therebetween. Any suitable solvent, adhesive, or the like may be used to adhere or bond the sleeve to the tube. Inflation aperture 80 extends through the wall of the tube, to provide a fluid flow path between the inflation lumen and the unadhered portion of the sleeve, to permit inflation of the balloon. The sleeve and recessed area preferably have the same length and the recessed area is preferably recessed an amount equal to the thickness of the sleeve, so that the exterior surface of the tube will be smooth and essentially uninterrupted after the sleeve is attached. The surface of the balloon and the distal end of the tube may be treated with any suitable release agent so as to prevent breaking of any clot that has formed when the inflation means is deflated and the device eventually withdrawn from the patient.

[0036] The third lumen 68 is of sufficient diameter to slidably receive the flow control device 60, and the relative lengths of the lumen 68 and device 60 are such that the distal end of the flow control device 60, containing the inflatable membrane 66, may be positioned at or beyond the distal end of the wound treating device 70. The flow control device 60 has, at its proximal end (not shown), a valve, such as the duck bill type valve shown in Figure 4A or conventional stopcock, to prevent deflation of the inflatable membrane 66 after pressurized fluid, such as sterile water, has been introduced by any suitable means, such as by syringe.

[0037] Figure 14B illustrates wound treating device 70 with a modified version of the retention means (balloon membrane) 84 in an inflated mode in the wound treating device 70 having a third lumen 68 formed therein. The placement of the third lumen 68 within the walls of the tube 108 is such that the membrane 66 of the flow control device, when inflated, will not interfere with the retention means 84 when it is also inflated, as illustrated and described below.

[0038] Figure 14B illustrates the introduction of a clotting agent 86 directly to the site of the wound to assist in forming a clot at the site of the vessel aperture. A quantity of clotting agent 86 is preferably located in the second lumen 82, for ejection onto the vessel opening or wound. When the treating agent is a clotting agent, it may be any of the suitable clotting agents presently commercially available. For example, the clotting agent 86 may be a thrombin agent. A thrombin agent is frequently used as a topical treatment by vascular surgeons to stop surface bleeding after a large incision is made in the body. By dispensing thrombin agent onto an aperture in an artery, bleeding from the aperture can be reliably hastened and stopped, reducing the risk of a hematoma, and eliminating the need for an overnight stay in the hospital. The treating agent, which is preferably in foam, powder, or gel form, may be pre-filled into the second lumen during manufacture or may be inserted into the second lumen at the time of the procedure.

[0039] The treating agent is deposited at the site of the aperture or wound from the distal end of the tube 72. The means, generally at 88, for dispensing the treating agent 86 is preferably a plunger 90. The plunger 90 has a distal end, generally at 98, and a proximal end, generally at 100. A rod 102 extends between the distal and proximal ends of the plunger. A piston or grommet 104 is located at the distal end of the rod 102 and a thumb rest 106 is provided on the proximal end. By advancing the plunger 90, the piston 104 forces the agent 86 from the distal end 74 of the tube 72. Calibrations may be provided on the rod and/or tube to provide an indication of the amount of agent dispensed and the rate of dispensing.

[0040] Figures 15A-F diagrammatically illustrate the additional embodiment of Figures 13-14 as it may be actually used. In Figure 15A, the sheath introducer 20 is advanced through the patient's skin S to the artery F. As discussed earlier, the sheath introducer 20 is normally inserted at the beginning of the angiographic or angioplasty procedure, and remains in position after the angiographic or angioplasty catheter is removed. The flow control device 60 is then inserted into the lumen of the introducer 20 until the distal end of the flow control device 60 is positioned within the artery F adjacent the site of the wound (Fig. 15B). During this step, the balloon membrane 66 is preferably, but not necessarily, in an invaginated position to permit the placement of the flow control device 60 within the artery F.

[0041] As shown in Figure 15C, the balloon membrane 66, at the distal end of the flow control device 60, is then inflated with sterile water or other fluid using the valve means (not shown) so as to cover or occlude the wound in the wall of the artery F. The inflated balloon membrane 66 is drawn against the opening in the artery F by gently pulling the tubular portion 62 back to block or substantially occlude the aperture or opening in the vessel made by the introducer 20. The introducer 20 may then be removed.

[0042] Figure 15D illustrates the next step in the procedure utilizing the alternative embodiment depicted in Figures 13 and 14. As shown there, the flow control device 60 helps to locate and guide the wound treating device into position in the vicinity of the aperture of the artery. Specifically, the tubular portion 62 of the flow control device 60 is inserted into the third lumen 68 of the wound treating device 70. The wound treating device 70

is then slid down the tubular portion until the distal end of the wound treating device 70 is generally in the vicinity of the opening or aperture in the artery wall F, which is at least partially occluded by the inflated balloon membrane 66.

[0043] As shown in Figure 15E, the inflatable retention means 84 is then inflated by means of pressurized sterile water or gas as previously described, so as to securely position the wound treating device 70 and to allow application of pressure if desired, in preparation for the introduction of the treating agent 86 to the wound site. The retention means 84 also serves to restrict blood flow from the vessel.

[0044] Figure 15F depicts application of treating agent 86 resulting from the depression of piston 104 of plunger 90. The inflated membrane 66, which at least partially occludes the vessel aperture, helps prevent the clotting agent from flowing into the vessel and helps maintain it between the balloon membrane 66 and the retention means 84. The treating agent 86, and the inflated balloon membrane 66 and retention means 84, together with the natural clotting process of the patient's body, act to stop the bleeding at the wound site. Alternatively, the balloon membrane 66 may be retracted before the introduction of the treating or clotting agent 86.

[0045] After clotting has taken place, inflatable membrane 66 may be deflated and the flow control device 60 retracted within the distal end 74 of third lumen 68. Following retraction of the flow control device, the retention means 84 of wound treating device 70 can also be deflated and withdrawn from the patient. To assist the treater in removing the wound treating device 70 after the clot is formed, the device 70 may be treated with a coating or release agent on its surface so as to enable the easy removal of the wound treating agent while minimizing the probability of clot breakage during removal.

[0046] While not shown in Figures 13 and 14, the tubular portion 62 of the flow control device 60 may also be inserted into the second lumen 82 instead of into a third lumen 68. In the operation of this embodiment, the wound treating device 70 is slid down along the flow control device 60 until the distal end of the wound treating device 70 is generally in the vicinity of the artery wall F at which time the inflatable means 84 is inflated. The inflatable balloon membrane 66 of the flow control.device 60 may then be retracted into the distal end of the flow control device 60, and the flow control device 60 withdrawn from the second lumen 70, or the balloon membrane may remain inflated within the vessel. A treatment or clotting agent may then be introduced via the second lumen 82 using a dispensing means, such as a plunger 90.

[0047] Figures 16A-C illustrate the alternative embodiment of the wound treating device 70 previously described in Figures 2 - 9, with the additional modification of the third lumen 68 formed within the walls of the elongated tube 108 (Figure 16A). The flow control device 60, which has essentially the same construction as previously described with reference to Figures 13A and 13B, is adapted to be inserted into the third lumen 68 (Figure 16B) such that the distal end of the flow control device 60 extends beyond the end portion of the elongated tube 28 and the treating agent 38. In this manner, the distal end of the elongated tube 28 may be positioned adjacent the wound site and outside the artery F, while the flow control device 60 is positioned adjacent the wound site and within the artery F.

[0048] Figures 16B and 16C, illustrate the inflation of flexible membrane 36, in the manner previously described and illustrated in Figures 2 - 4, using pressurized liquid or air, which is introduced into the tube 28 by means of the plunger or piston 46. As the piston 46 moves forward, it inflates the flexible membrane 38 and ejects the treating agent 38, in the manner previously described and shown in Figures 2 - 9, onto the wound.

[0049] Figures 17A-D illustrate this further embodiment of the invention as it may be used. As shown in Figure 17A, the flow control device 60 extends beneath the opening in the wound into the artery F. After penetrating the artery F and inflating the balloon membrane 66, the tubular portion 62 of flow control device 60 is gently pulled backwards so that the balloon means 66 abuts and occludes the wound opening in the wall of the artery F. As described earlier, the distal end of the wound treating device is positioned generally adjacent to the opening in the artery F. The wound treating device is inserted over the tubular portion of the flow control device and into the incision leading to the wound site. The flexible membrane 36 of the treating device is maintained in a pocket, in which the treating agent may be located, as previously disclosed and described in Figure 2.

[0050] In the next step in the procedure as shown in Figure 17B, the flexible membrane 36 is inflated by the insertion of air or fluid using the plunger 46, in the manner previously illustrated in Figure 4 and described in the corresponding portion of the specification, thus pushing the treating agent 38 out the distal end of the tube 28 to the site of the wound in the artery F. The flexible membrane 36, the treating agent 38, and the inflatable balloon membrane 66 work together to bring about the cessation of bleeding in a faster and more efficient manner. As the inflated balloon membrane 66 occludes the wound, the treating agent 65 assists the body's natural clotting process, providing a more rapid closure of the wound. Alternatively, the balloon membrane 66 may be retracted before the introduction of the treating or clotting agent 38.

[0051] Figure 17C depicts the flexible membrane 36 and the inflatable balloon membrane 66 in the inflated mode, with the treating agent 38 having been placed over the wound surface in the artery F. The inflated flexible membrane 36 secures the tube 28 in the desired position and allows pressure to be applied to the site if desired. The flow control device 60 is maintained against the inside surface of the artery F to block or sub-

stantially reduce the flow of blood; thus giving the treating agent and the patient's own clotting process the opportunity to close the wound.

[0052] Figure 17D illustrates the final step of the procedure following at the conclusion of the clotting process. After closure of the wound is substantially completed, the inflatable balloon membrane 66 is deflated by the removal of air or water through the valve means (not shown), such as the duckbill valve previously discussed. Similarly, the flexible membrane 36 of the treating device is deflated in the manner previously described, and retracted t the invaginated position within the tube 28. The treater may then retract the now deflated balloon membrane 66 through the elongated tube 60, and remove the tube 28 from the skin of the patient. A release agent or material may coat the membrane 66 and end of the elongated tube 60 to ease removal of the flow control device without breaking the clot. With the treating agent 38 assisting the natural clotting process occurring in the body, the wound is now closed in a much shorter time than previously obtainable using prior art technology.

[0053] Although the preferred construction of the treating device is described above, various changes may be made without departing from the present invention. The features of the wound treating device and method of the present invention have been described in connection with the accompanying drawings for purposes of illustration and not limitation. It is intended that this application include those modifications, variations and additions that would be readily apparent to one of ordinary skill upon reading this description. Accordingly, for ascertaining the scope of the present invention, reference must be made to the appended claims.

Claims

1. A wound treating device comprising:

   a tubular portion having a proximal end, a distal end and a lumen extending therebetween;

   inflatable means cooperatively associated with said distal end of said tubular portion, said inflatable means comprising a first flexible membrane carried at said distal end of said tubular portion and being positionable within said distal end and movable between a retracted position and an inflated position to form a balloon-like projection at said distal end when moved to the inflated position; and

   said proximal end of said tubular portion being adapted to receive means for moving said inflatable means between said retracted position and said inflated position;

   wherein said first membrane is positionable within said second lumen and when in said retracted position to form a pocket;

   and further comprising a wound treating agent held within said pocket.

2. The wound treating device of Claim 1, wherein said first flexible membrane has a clot-promoting surface.

3. The wound treating device of Claim 1, wherein a release agent is disposed on said first flexible membrane.

4. The wound treating device of any of claims 1 to 3, wherein a wound treating agent is disposed on the surface of said first flexible membrane.

5. The wound treating device of any of claims 1 to 4, wherein said wound treating agent has clot promoting properties.

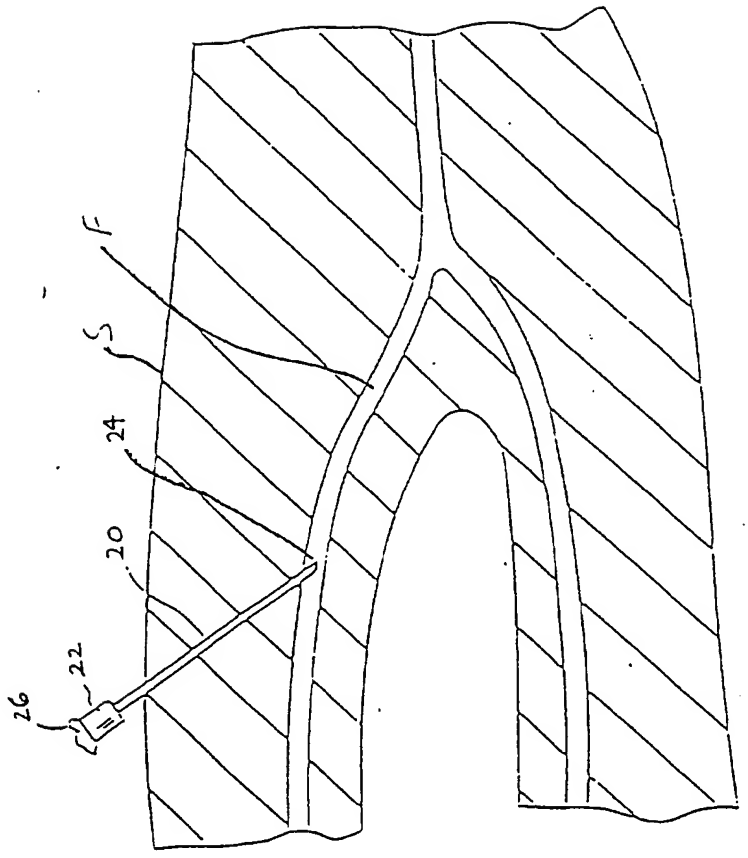


FIG. 1

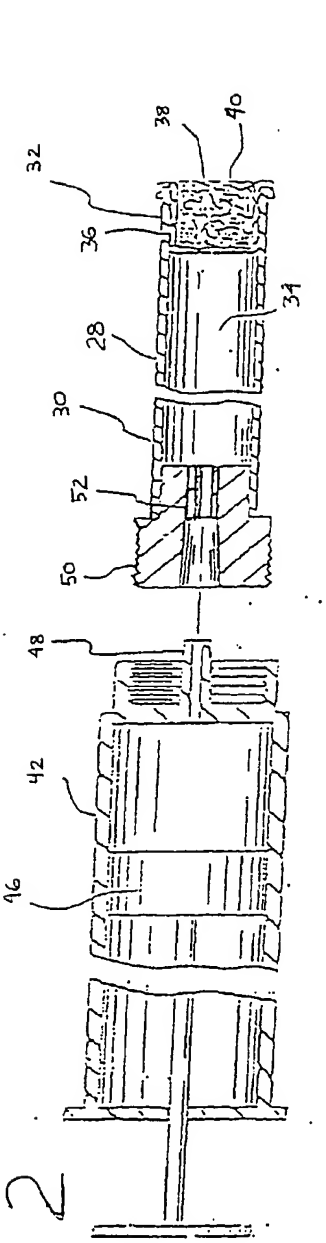


FIG 2

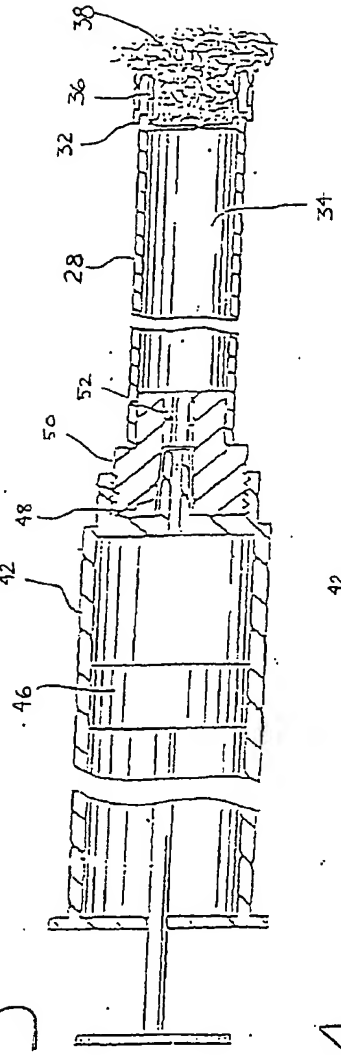


FIG 3

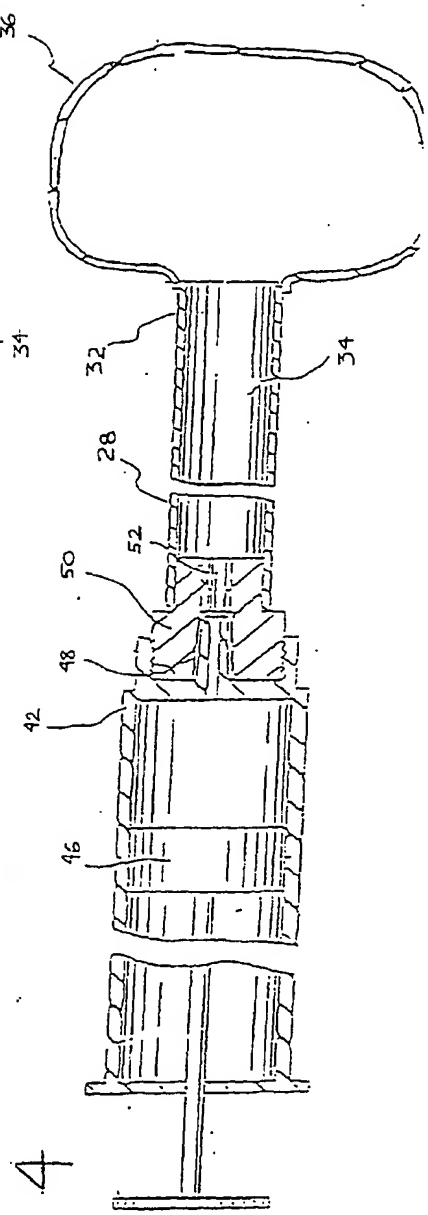


FIG 4

FIG. 5

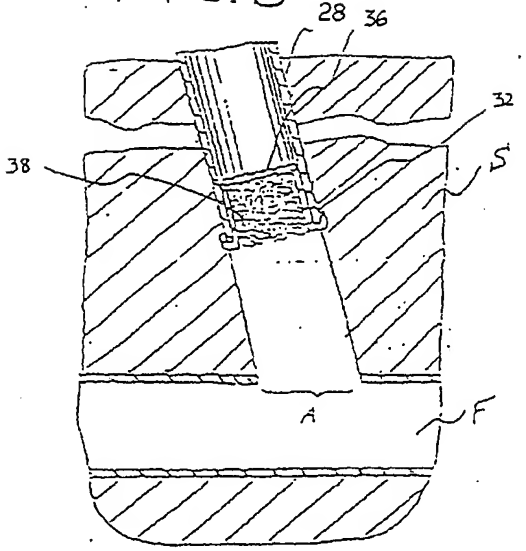


FIG. 6

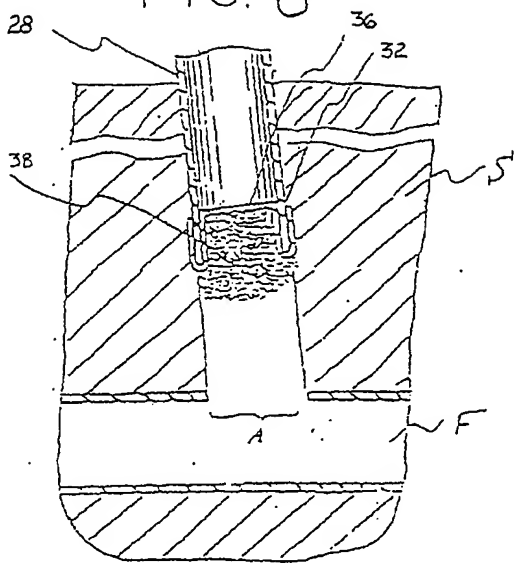


FIG. 7

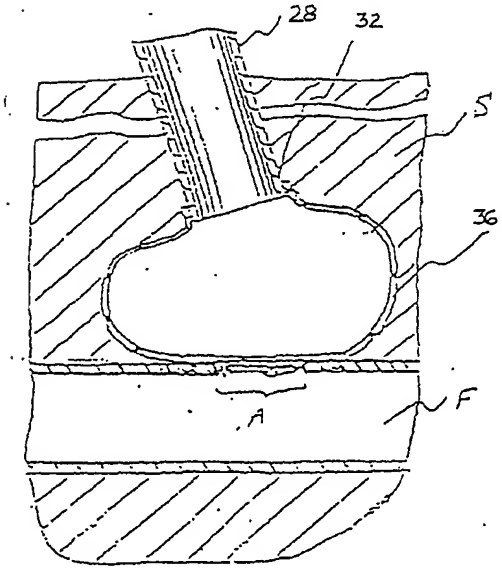


FIG. 8

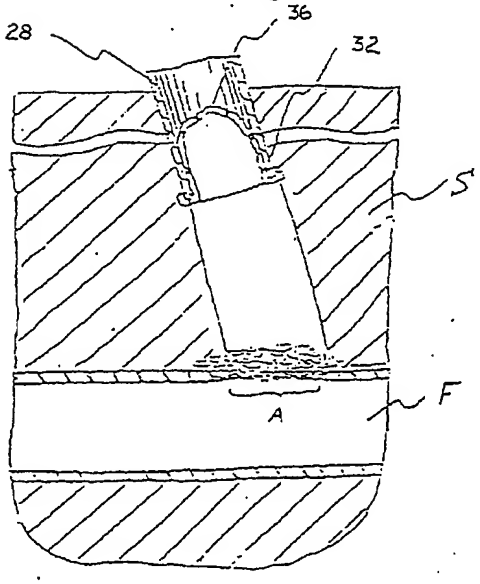


FIG. 9

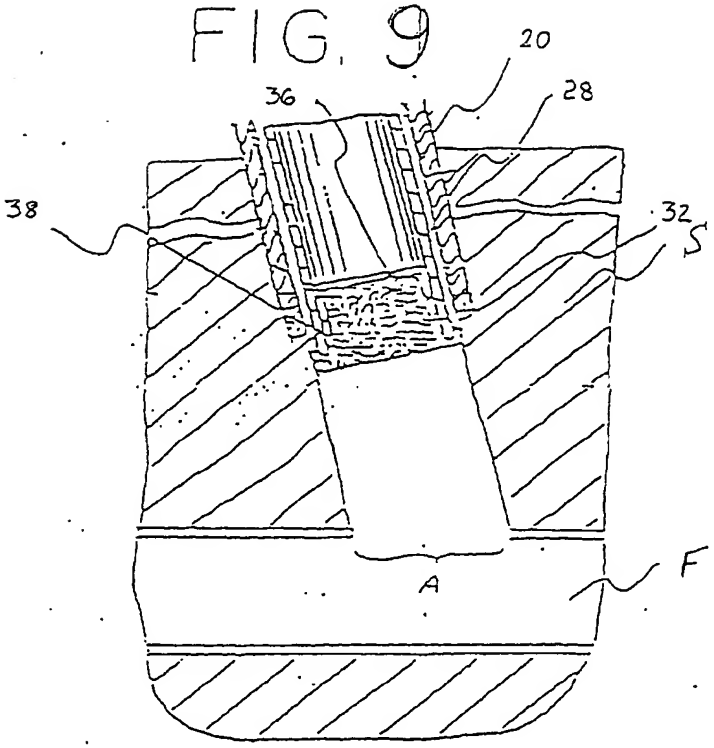
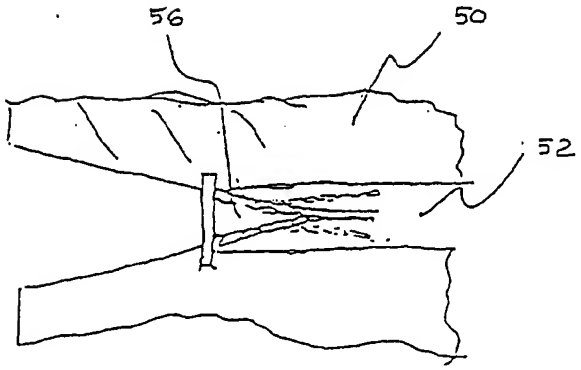


FIG. 4A



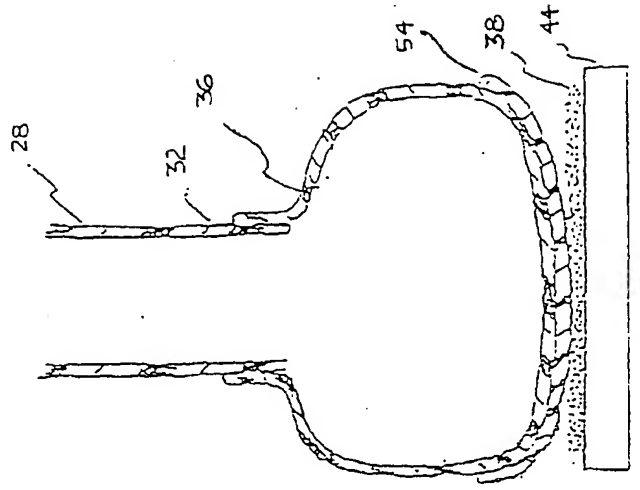


FIG. 10C

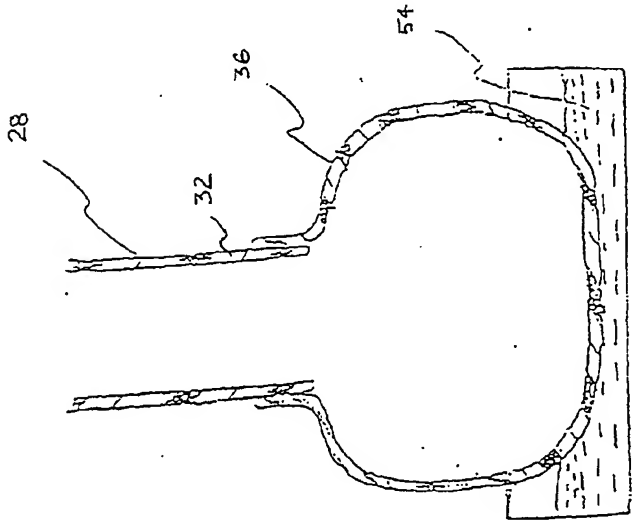


FIG. 10B

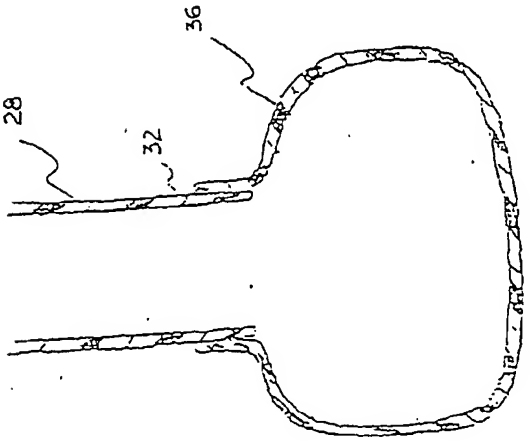


FIG. 10A

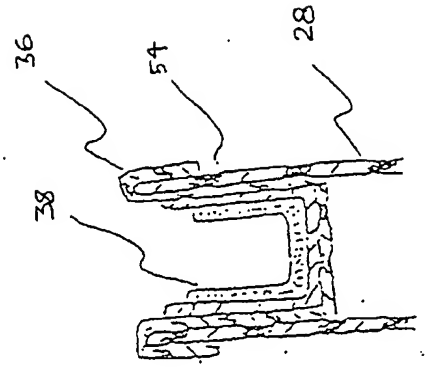


FIG. 12

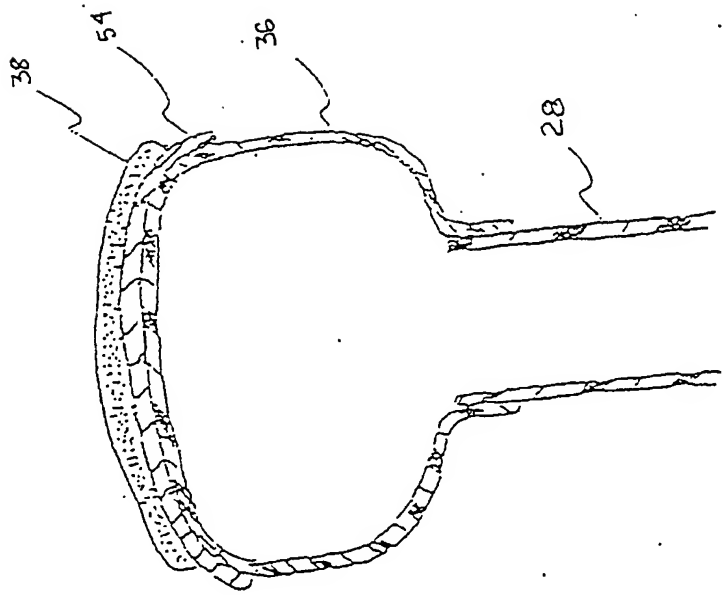


FIG. 11

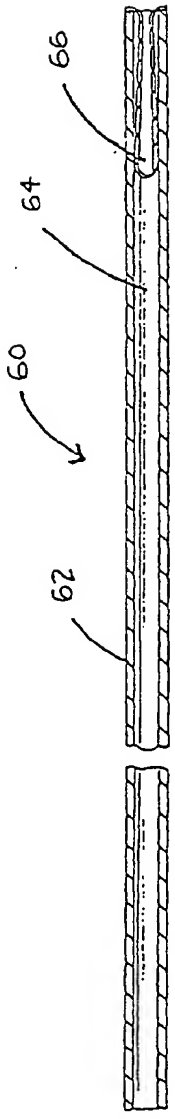


FIG. 13A

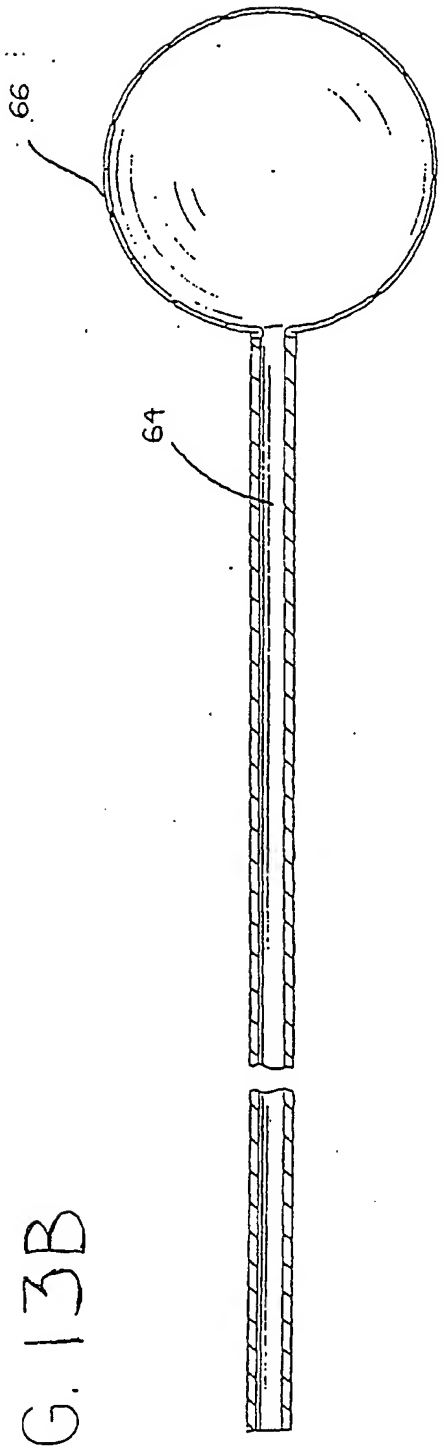


FIG. 13B

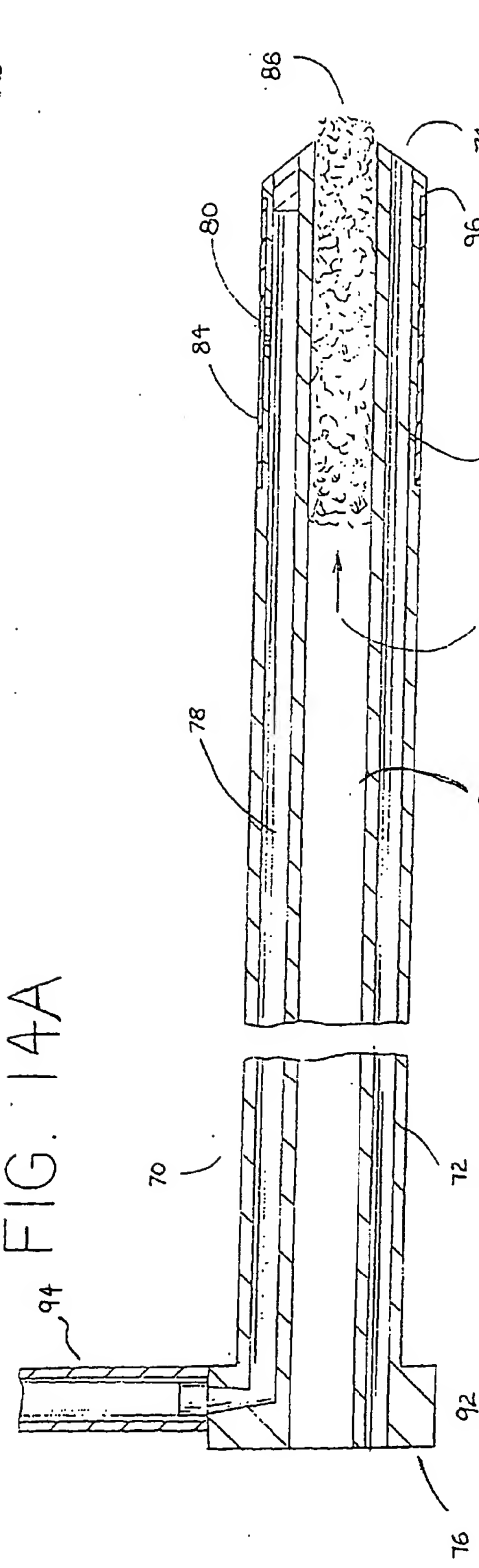


FIG. 14A

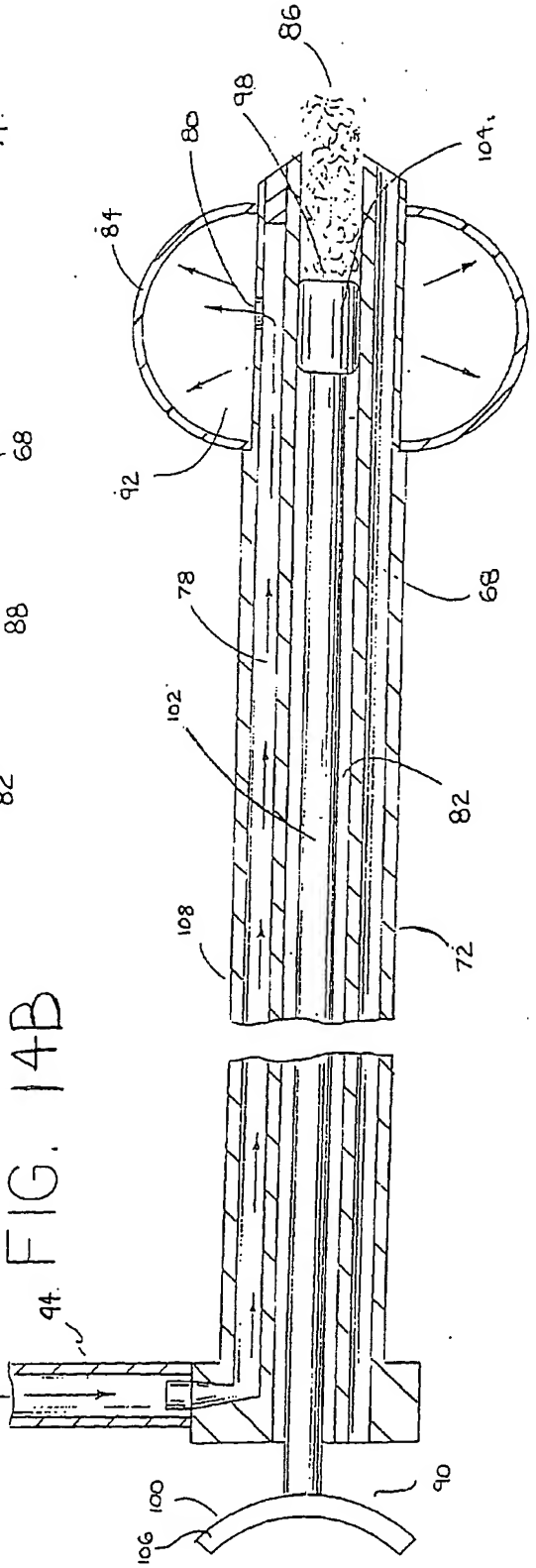


FIG. 14B

FIG. 15B

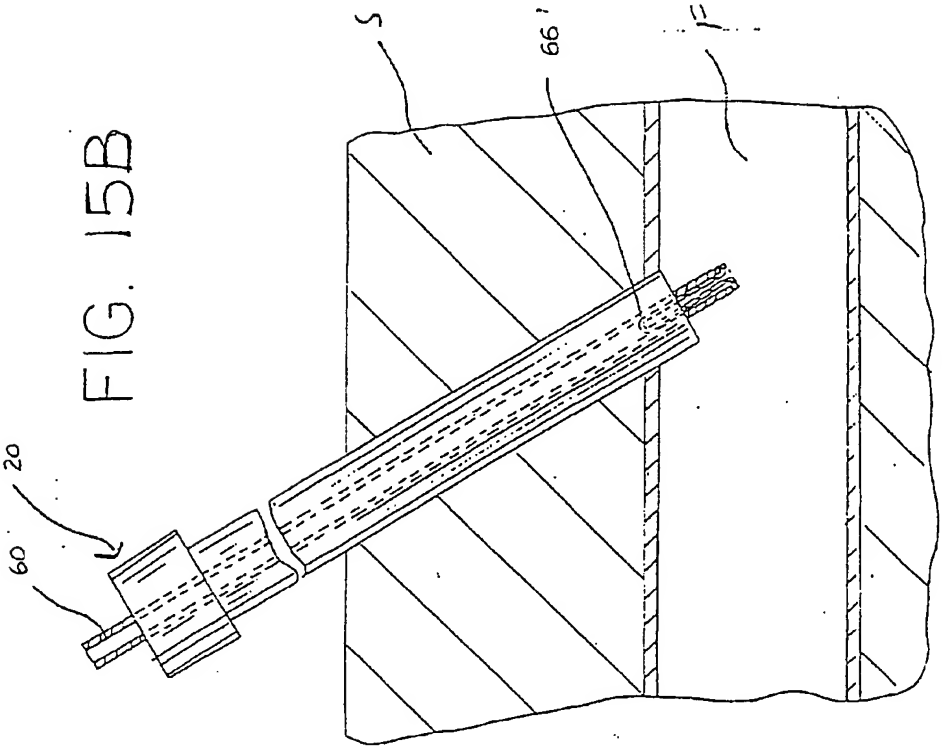


FIG. 15A

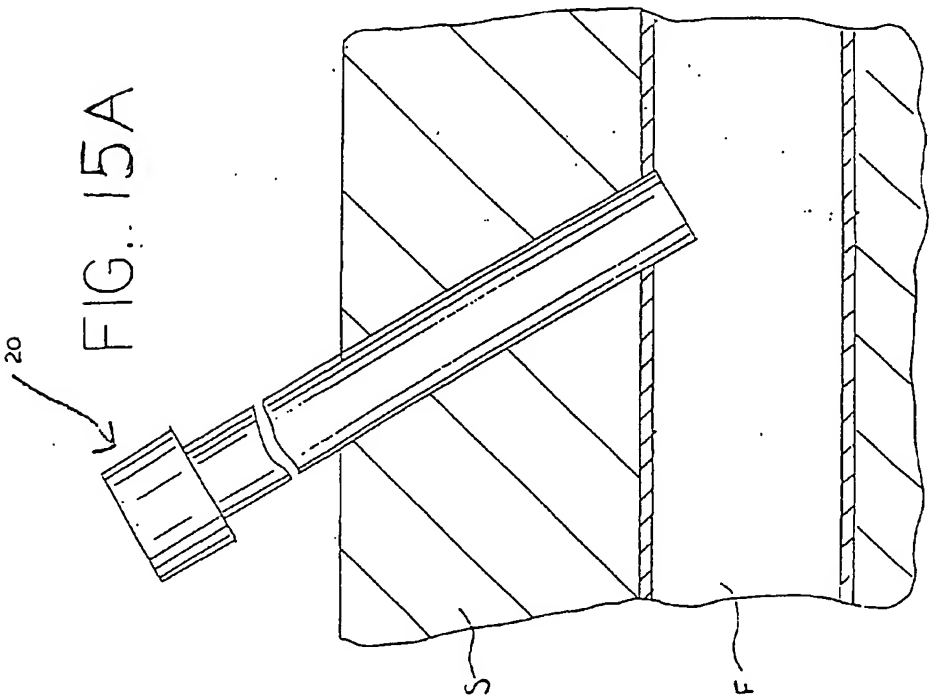


FIG. 15D

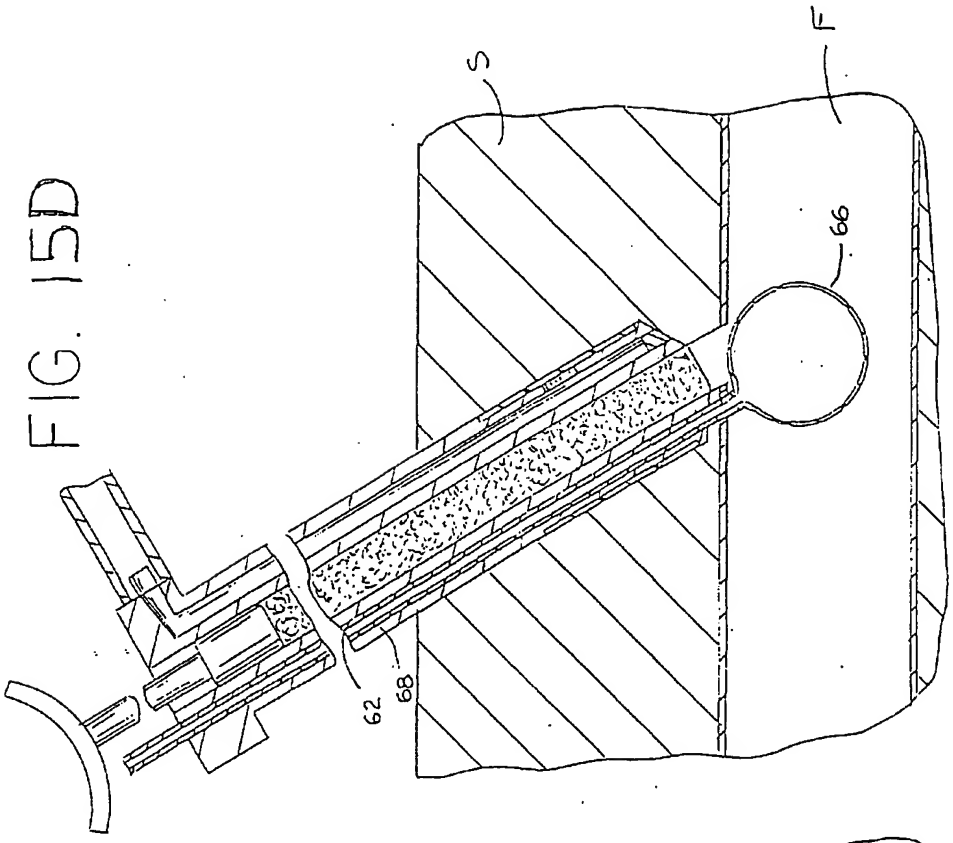


FIG. 15C

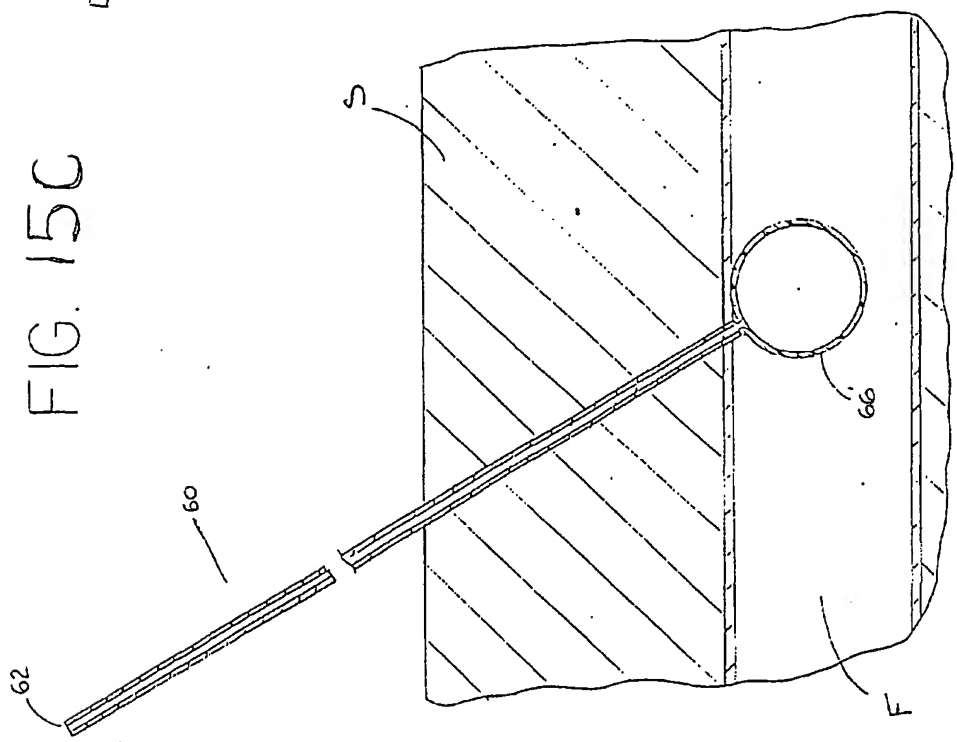


FIG. 15F

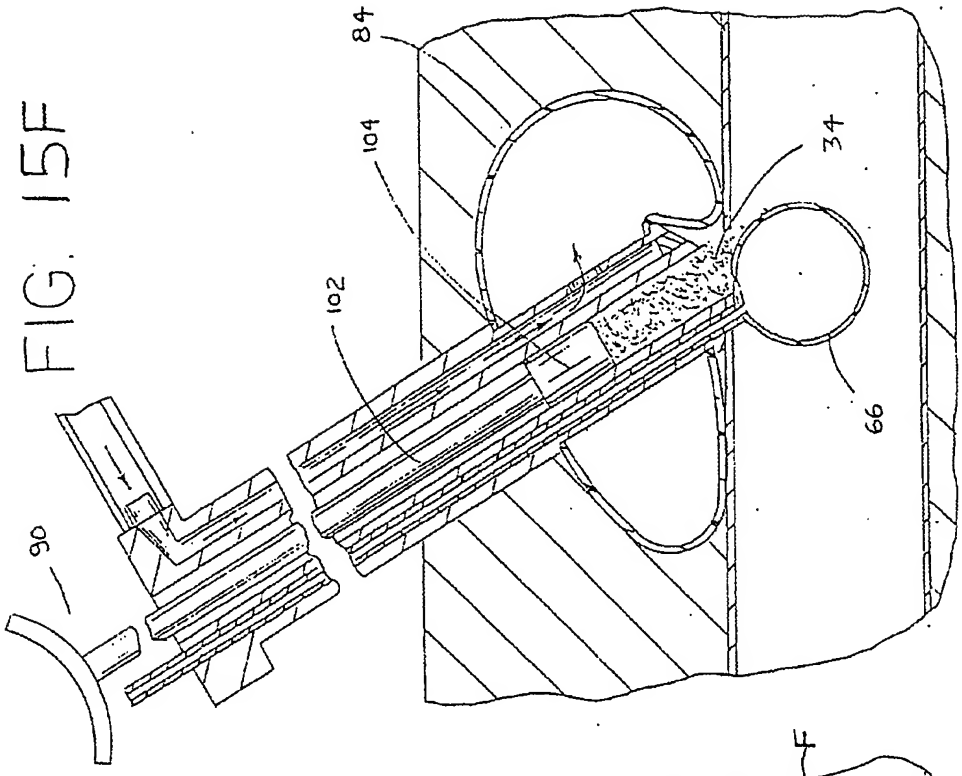
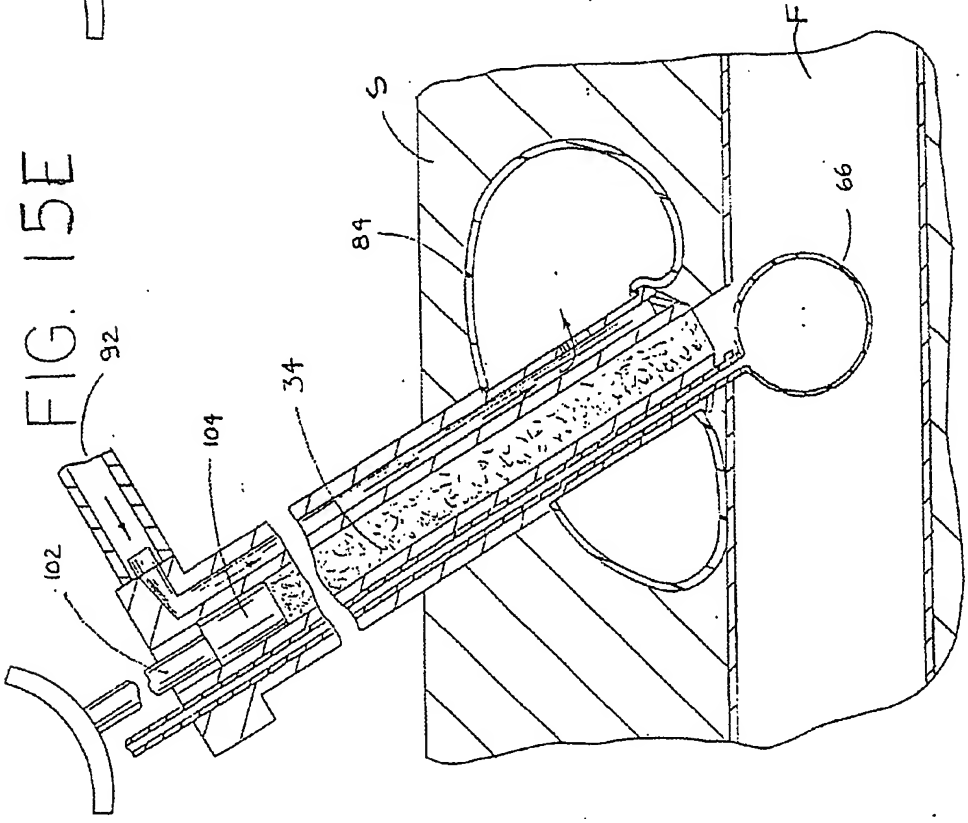


FIG. 15E



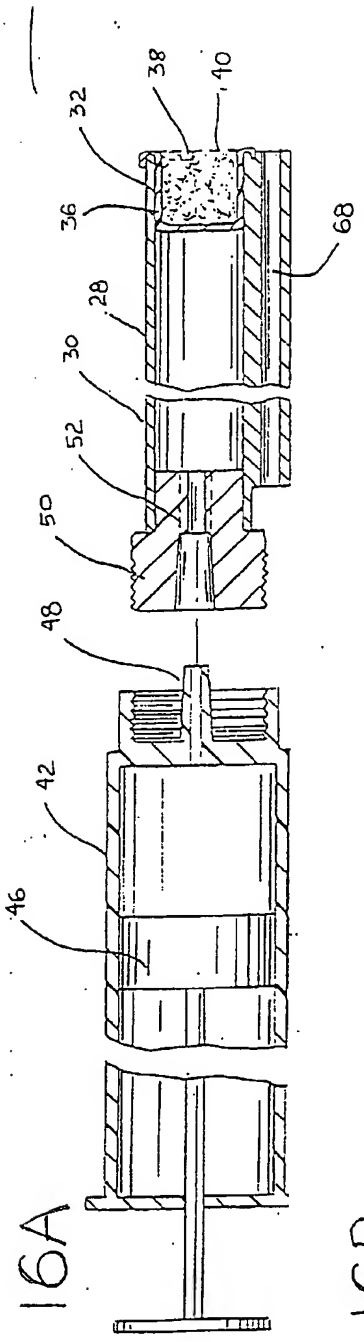


FIG. 16A

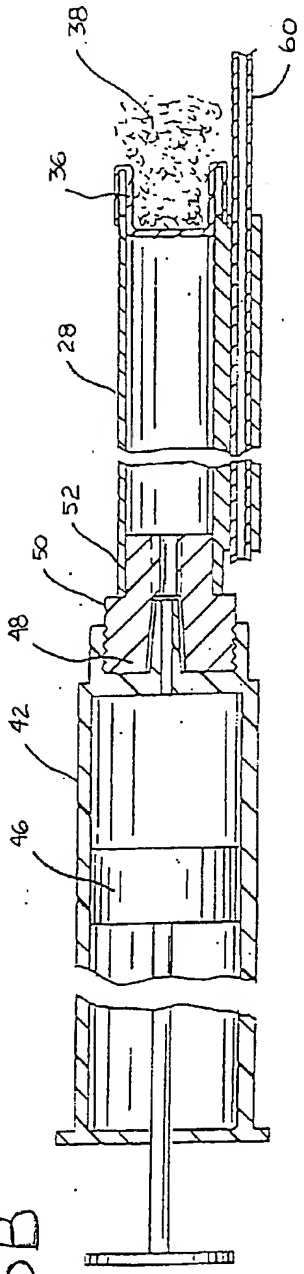


FIG. 16B

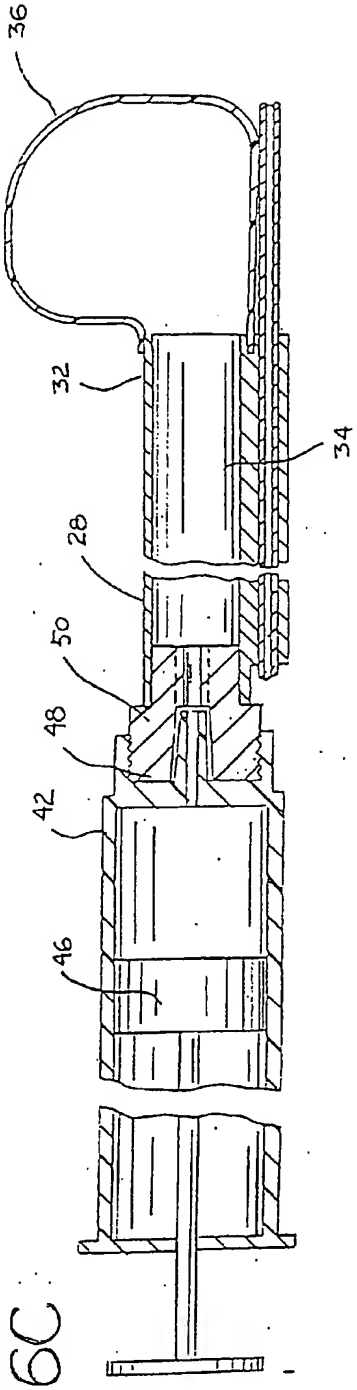


FIG. 16C

FIG. 17A

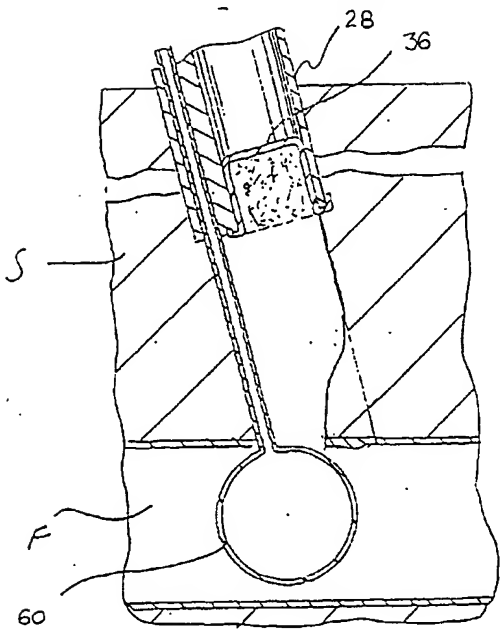


FIG. 17B

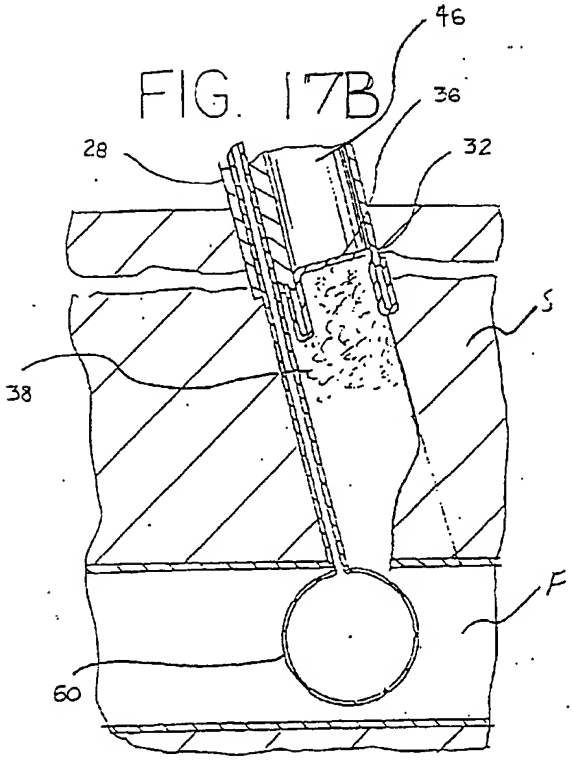


FIG. 17C

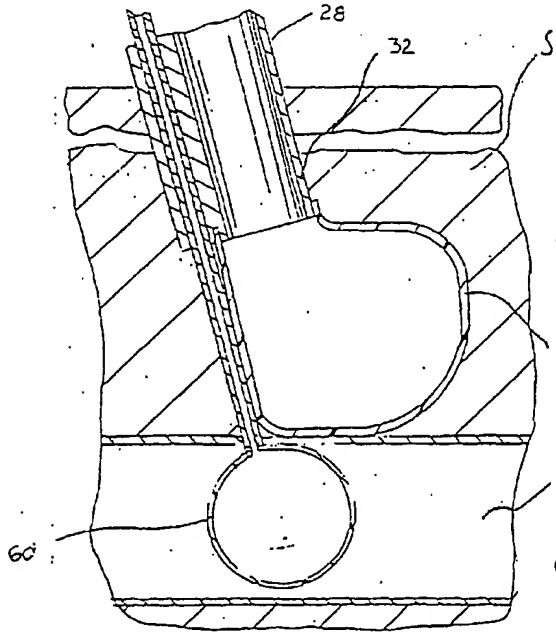
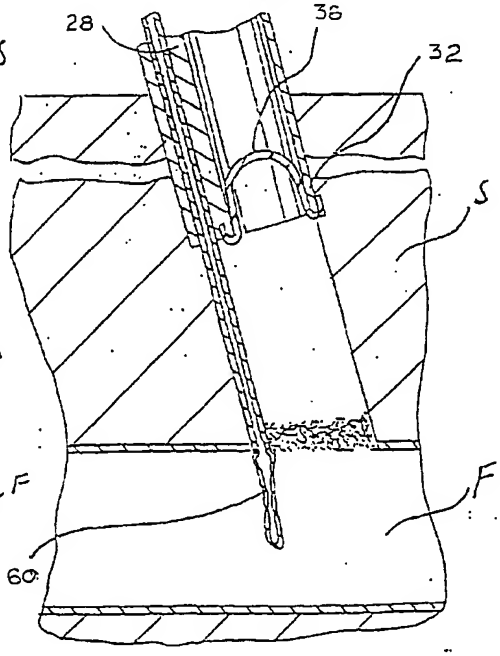


FIG. 17D



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EUROPEAN SEARCH REPORT

Application Number
EP 01 11 9163

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	EP 0 493 810 A (NOVOSTE CORP.) 8 July 1992 (1992-07-08) * abstract; claims 1-5,13; figures 2-7 *	1-4	A61M25/01 A61B17/00
A	US 4 493 711 A (CHIN ET AL.) 15 January 1985 (1985-01-15) * abstract * * column 1, line 35 - line 37; figures 1,3-6 *	1,3	
A	EP 0 402 467 A (TERUMO CORP.) 19 December 1990 (1990-12-19) * abstract; figures 1,5,6 *	1	
A	US 4 445 892 A (LOEB ET AL.) 1 May 1984 (1984-05-01) * abstract; figures 1,4-6 *	1	
A	US 4 638 803 A (RAND) 27 January 1987 (1987-01-27) * abstract; claim 1; figures 1-3 *	1,2,4,5	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
A	EP 0 372 088 A (SUMITOMO ELECTRIC INDUSTRIES, LTD) 13 June 1990 (1990-06-13) * abstract * * page 3, line 7 - line 10; figure 1 *	1,3	A61M A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	31 August 2001	Michels, N

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